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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,121	04/07/2006	Elena Feinstein	71212-A-PCT-US/JPW/JW	1972

23432 7590 03/09/2009

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
03/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,121	FEINSTEIN ET AL.	
	Examiner	Art Unit	
	KIMBERLY CHONG	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *26-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Furthermore, under PCT Rule 13.2 the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 26-29 and 37-39, drawn to a double stranded oligoribonucleotide wherein on strand comprises any of SEQ ID Nos. 3-45, and 67. This group is subject to a further restriction below.

Group II, claim(s) 30, 31, 33, 34, 36, 40, 41, and 43-45, drawn to a method treating a neurodegenerative disease in a subject comprising a BMP2A inhibitor wherein the inhibitor is a siRNA, wherein the siRNA has a sequence set forth in any of

SEQ ID Nos. 25-45, 67, 1-2, 4-6, 14-16 or 18-22. . This group is subject to a further restriction below.

Group III, claim(s) 30, 31, 33, 35, 36, 41, 43, 44 and 45, drawn to a method treating a neurodegenerative disease in a subject comprising a BMP2A inhibitor wherein the inhibitor is a siRNA, wherein the siRNA has a sequence set forth in any of SEQ ID Nos. 1 or 2. This group is subject to a further restriction below.

Group IV, claim(s) 30-32, 36, and 42, drawn to a method treating a neurodegenerative disease in a subject comprising a BMP2A inhibitor wherein the inhibitor is an antisense compound.

The inventions listed as Group I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of groups I and II is a double stranded oligoribonucleotide comprising SEQ ID No. 67 wherein a base is altered in up to 2 nucleotides in each terminal region. The double stranded oligoribonucleotide cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. U.S. Patent Application 20050255487 teach a double stranded oligoribonucleotide wherein the oligoribonucleotides comprise 18 consecutive nucleotides of SEQ ID No. 7 (see sequence alignment below). The limitation "wherein a base is altered in up to 2 nucleotides in each terminal region" is interpreted to mean the base can be a different nucleotide in the terminal region. The double stranded oligoribonucleotide taught in

U.S. Patent Application 20050255487 is 19 nucleotides in length wherein one terminal end nucleotide is modified or different as compared to the claimed sequence. Further the specification of U.S. Patent Application 20050255487 teach the double stranded oligoribonucleotide can comprise altered modifications and bases at the terminal ends (see entire specification).

The inventions listed as Group I and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of groups I is an oligoribonucleotide comprising SEQ ID Nos. 3-45 or 67. The special technical feature of group II is an oligonucleotide agent comprising SEQ ID Nos. 1 or 2 and therefore groups I and III do not have the same special technical feature.

The inventions listed as Group I and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of groups I is a siRNA molecule. The special technical feature of group IV is an antisense molecule and therefore groups I and IV do not have the same special technical feature.

The inventions listed as Group II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of groups I is an oligoribonucleotide comprising SEQ ID Nos. 3-45 or 67 capable

of use in the methods of treating a neurodegenerative disease. The special technical feature of group II is an oligonucleotide agent comprising SEQ ID Nos. 1 or 2 capable of use in the methods of treating a neurodegenerative disease and therefore groups I and III do not have the same special technical feature.

The inventions listed as Group II and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of groups II is a siRNA molecule. The special technical feature of group IV is an antisense molecule and therefore groups II and IV do not have the same special technical feature.

The inventions listed as Group III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of groups III is a siRNA molecule. The special technical feature of group IV is an antisense molecule and therefore groups III and IV do not have the same special technical feature.

The claims are further restricted as follows:

Chemical Compound Alternatives of Markush Group Are Not of a Similar Nature.

Where a single claim defines alternatives of a Markush group, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity; AND

(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

The oligoribonucleotide compounds of Groups I, II and III are not regarded as being of similar nature because all of the alternatives do not share a common property or activity. Should Groups I, II or III be elected, oligoribonucleotides having SEQ ID Nos. as claimed are distinct inventions and one (1) must be selected. The search and examination of all agents is burdensome because the searches are not coextensive.

Sequence alignment

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       US-10-940-892-2239259/c
; Sequence 2239259, Application US/10940892
; Publication No. US20050255487A1
; GENERAL INFORMATION:
;  APPLICANT: Dharmacon, Inc.
;  APPLICANT:  Khvorova, Anastasia
;  APPLICANT:  Reynolds, Angela
;  APPLICANT:  Leake, Devin
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;  APPLICANT:  Marshall, William
;  APPLICANT:  Read, Steven
;  APPLICANT:  Scaringe, Stephen
;  TITLE OF INVENTION: Methods and Compositions for Improving
;  TITLE OF INVENTION:  siRNA Functionality
;  FILE REFERENCE: 13608PCT
;  CURRENT APPLICATION NUMBER: US/10/940,892
;  CURRENT FILING DATE:  2004-09-14
;  NUMBER OF SEQ ID NOS: 2675299
;  SOFTWARE: Proprietary
; SEQ ID NO 2239259
;   LENGTH: 19
;   TYPE: RNA
;   ORGANISM: Homo sapiens
;   FEATURE:
;   NAME/KEY: misc_RNA
;   LOCATION: (1)...(19)
;   OTHER INFORMATION: siRNA sense strand
US-10-940-892-2239259

  Query Match             94.7%;  Score 18;  DB 19;  Length 19;
  Best Local Similarity   100.0%;  Pred. No. 82;
  Matches   18;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 TGCCTTAGGAATCTTAGA 18
              ||||||||||||||||||
Db         18 TGCCTTAGGAATCTTAGA 1
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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Additionally, **claim 35 improperly refer to sequences in tables**. MPEP 2173.05(s) states in part " [w]here possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim". Applicant is required to refer to the sequences, in the claims, by the appropriate sequence identifier.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635